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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------|-------------|----------------------|---------------------|------------------|
| 09/245,625 | 02/05/1999 | ROBERT R. BURCH | BUR-020 | 5098 |
| 31344 | 7590 | 09/09/2004 | EXAMINER | |
| RATNERPRESTIA | | | BERKO, RETFORD O | |
| P.O. BOX 1596 | | | ART UNIT | |
| WILMINGTON, DE 19899 | | | PAPER NUMBER | |

1615

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/245,625

Applicant(s)

BURCH ET AL.

Examiner

Retford Berko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 10, 14, 19 and 30-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1, 10, 14, 19 and 30-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Acknowledgement: Applicant's amendment and RCE filed May 17, 2004 following a decision by the BPAI rendered on March 3, 2004 is acknowledged.

Status of Claims

The status of the claims is as follows:

- a. Claims 1, 10, 14, 19 and 30-45 are pending in this RCE.
- b. Claims 2-9, 11-13, 15-18 and 20-29 are cancelled in view of applicant's amendment.
- c. Applicant's amendment and RCE are validly entered by the examiner pursuant to the requirements of 37 CFR 1.198, and;
- d. In accordance with the provisions of 37 CFR 1.114, the prosecution of this application is reopened following the BPAI decision rendered on said application on March 23, 2004.

Claim Rejections-Sec 112

Grounds for Rejection: New Matter.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 10, 14 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The claims recite a fiber comprising elastomeric polymer in which the fiber has a core of segmented polymer and the segmented polymer has hard segments (urethane and soft segment (polyester, polyether or mixture) wherein the said hard and soft segments are held together by covalent bonds. According to the specification (page 3, lin 20-25) the fiber has a preferred denier value of about 40-4,000; preferably about 200 to 2, 500; more preferably about 800-2, 400 and the fiber has elongation of 300%; and therefore,

a. Claims 1, 10, 14 and 19 are rejected under 35 U.S.C. 112, first paragraph because the claims have introduced new matter as the specification does not support the denier values having the range of 40-4, 000.

b. Claims 1, 10, 14 and 19 are rejected under 35 U.S.C., first paragraph because the claims have introduced new matter as the specification does not support a break elongation of 200% and break elongation of at least 400%.

Applicant may overcome the rejections by pointing out the section(s) of the specification as filed showing support for the new matter introduced into the claims, remove the new matter from the claims or cancel the claims.

Claim Rejections-35 USC Sec. 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 10, 14, 19, and 30-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burch et al (US 5, 433, 226) in view of Hill (US 5, 098, 711) further in view of Erikson et al (US 5, 499, 917).

The claims are directed toward a fiber comprising an elastomeric polymer capable of imbibing a chemotherapeutic agent (therapeutically effective amount) wherein the fiber has a core of a segmented polymer. The claims are also directed toward the segmented polymer having soft segment (polyester, polyether or mixture) and a hard segment (urethane); wherein the soft and hard segments are held together by covalent bonds and wherein the fiber has imbed or dispersed therein chemotherapeutic agents (e.g. a fluoride salt of known ppm) and said fiber having specified physical characteristics such as denier value, tensile strength and break elongation values. The claims are further directed toward a method for preparing a fluoride containing fiber, assembling such fiber into a dispensing box or kit containing dental floss made of comprising said fibers, wherein the fibers are continuous strands.

Burch et al (Patent '226) disclose the limitations in instant claim 1. Patent '226 discloses dental floss fiber having a core of segmented polymer wherein the polymer has soft segments and hard segment joined by covalent bonds (abstract, col 3, lin 35-50; col5, lin 35-60 and Patent

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claims 1, and 8-9 at col 11, lin 20-25). As in applicant's claim 1, the soft segment is made of polyether and polyester and the hard segment is made of urethane (Patent claim 23 at col 12, lin 60-65). As in applicant's claim 1, Patent '226 discloses the physical characteristics—e.g. denier,, tensile strength and break elongation values (Patent claims 22 at col 12, lin 50). According to applicant's examples in the specification (page 4, lin 30 and pages 13-17) spandex or Lycra are polymers used for making dental floss fibers---as Patent '226 discloses the use of these polymers in the invention, Patent '226 disclose the physical characteristics of the fibers as in the instant claims (col 7, lin 15-65 and col 6, lin 5-25) and also discloses dental floss kit or box for dispensing the dental devices (col 9, lin 25 and col 10, lin 10-20).

Patent '226 does not disclose the use of a drug, medicament or therapeutic agent in the polymer or fibers.

Hill et al (Patent '711) discloses a method of treating dental cavities, gingivitis and perodontitis (abstract, Patent claim 11 at col 40, lin 30-50, continuing to Patent claims 12 and 13 at col 41 and col 42) with chemotherapeutic agents released from multi-strand dental floss comprising filaments (col 12, lin 10-20). More significantly, according to Hill et al, antibiotics, chemicals such as stannous fluoride, anti-plaque or anti-gingivitis agents, buffering agents and other ingredients can be introduced (col, 15, lin15) added (col 15, lin 36 and col 18, lin 36) or loaded (col 19, lin 13-30 and col 20, lin 30-40). Giving broad interpretation to applicant's claims, examiner takes the position that the language used in Patent '711 wherein chemicals and ingredients are introduced or added or loaded into the fibers is for all intent and purposes deemed to be equivalent's claim language wherein the fibers are capable of "imbing" chemotherapeutic agents.

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Erikson et al (Patent '917) disclose an invention wherein elastic fibers are arranged as a dental device (dental dam), said dental fibers are of type called Lycra XA 700 or spandex fibers (col 3, lin 45-65; col 7, lin 50-55 and col 8, lin 10-15). Most significantly, Patent '917 specifically discloses that medicaments e.g. bactericidal agents and/or fungicidal agents and other agents that will be apparent to those skilled in the art may be added to the fibers as desired (col 4, lin 31-37).

One of ordinary skill in the art would have been motivated to make a floss or dam comprising Spandex or Lycra fibers as dental floss devices and add, introduce or load into said fibers chemotherapeutic agents such as antibacterial, anti-gingivitis and anti caries agents (e.g. stannous fluoride or sodium fluoride). One of ordinary skill would expect to obtain reasonable success in obtaining a dental floss that would be as easy to use and enhance patient comfort during usage as was achieved in Patent '971 (col 7, lin 20-40). More importantly, the motivation to combine the prior art references cited lies in the fact that one of ordinary skill would be undoubted to find it useful or desirable and indeed beneficial to add chemotherapeutic agents to the dental fibers in order to control dental infection and dental diseases through application of said dental floss made of fibers having known dental prophylactic or chemical agents impregnated therein as this was suggested by Erikson et al (Patent '917, col 4, lin 31-37). Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill at the time it was made.

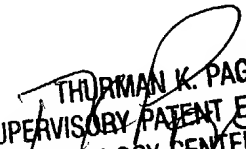
Correspondence

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER T600